

CENTER FOR DRUG EVALUATION AND RESEARCH

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Nicotine Polacrilex Gum USP, 4 mg (nicotine)

Nicotine Polacrilex Gum Usage Instructions

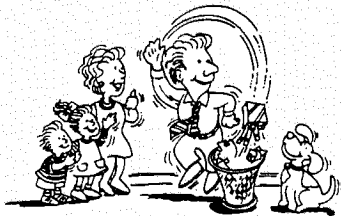
**HOW TO USE
NICOTINE POLACRILEX GUM
TO HELP YOU QUIT SMOKING**

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- **NOT for sale to those under 18 years of age.**
- **Proof of age required.**
- **Not for sale in vending machines or from any source where proof of age cannot be verified.**

KEYS TO SUCCESS.

- 1) You must really want to quit smoking for **Nicotine Polacrilex Gum** to help you.
- 2) You can greatly increase your chances for success by using at least 9 to 12 pieces every day when you start using **Nicotine Polacrilex Gum**. (See page 10)
- 3) You should continue to use **Nicotine Polacrilex Gum** as explained in this User's Guide for 12 full weeks.
- 4) **Nicotine Polacrilex Gum** works best when used together with a support program. (See page 3)
- 5) If you have trouble using **Nicotine Polacrilex Gum**, ask your doctor or pharmacist, or call Watson at 1-877-JUS-STOP.



SO YOU DECIDED TO QUIT.

Congratulations. Your decision to stop smoking is an important one. That's why you've made the right choice in choosing **Nicotine Polacrilex Gum** (pronounced "nik'-ah-teen poh-lah-cry'-lex gum").

Your own chances of quitting smoking depend on how much you want to quit, how strongly you are addicted to tobacco,

and how closely you follow a quitting program like the one that comes with **Nicotine Polacrilex Gum**.

QUITTING SMOKING IS HARD!

If you've tried to quit before and haven't succeeded, don't be discouraged! Quitting isn't easy. It takes time, and most people try a few times before they are successful. The important thing is to

try again until you succeed. This User's Guide will give you support as you become a non-smoker. It will answer common questions about **Nicotine Polacrilex Gum** and give tips to help you stop smoking, and should be referred to often.

WHERE TO GET HELP.

You are more likely to stop smoking by using **Nicotine Polacrilex Gum** with a support program that helps you break your smoking habit. There may be support groups in your area for people trying to quit. Call your local chapter of the American Lung Association, American Cancer Society or American Heart Association for further information. Toll free numbers are printed on the Wallet Card on the back cover of this User's Guide.

If you find you cannot stop smoking or if you start smoking again after using **Nicotine Polacrilex Gum**, remember breaking this addiction doesn't happen overnight. You may want to talk to a health care professional who can help you improve your chances of quitting the next time you try **Nicotine Polacrilex Gum** or another method.

LET'S GET ORGANIZED.

Your reason for quitting may be a combination of concerns about health, the effect of smoking on your appearance, and pressure from your family and friends to stop smoking. Or maybe you're concerned about the dangerous effect of second-hand smoke on the people you care about.

All of these are good reasons. You probably have others. Decide your most important reasons, and write them down on the wallet card inside the back cover of this User's Guide. Carry this card with you. In difficult moments, when you want to smoke, the card will remind you why you are quitting.

WHAT YOU'RE UP AGAINST. Smoking is addictive in two ways. Your need for nicotine has become both physical and mental. You must overcome both addictions to stop smoking. So while **Nicotine Polacrilex Gum** will lessen your body's physical addiction to nicotine, you've got to want to quit smoking to overcome the mental dependence on cigarettes. Once you've decided that you're going to quit, it's

time to get started. But first, there are some important cautions you should consider.

SOME IMPORTANT CAUTIONS. This product is only for those who want to stop smoking.

Do not smoke, chew tobacco, use snuff or nicotine patches while using **Nicotine Polacrilex Gum**.

If you have heart disease, a recent heart attack, irregular heartbeats, palpitations, high blood pressure not controlled with medication, stomach ulcer, or take insulin for diabetes, ask your doctor whether you should use **Nicotine Polacrilex Gum**.

As with any drug, if you are pregnant or nursing a baby, seek the advice of

a health professional before using this product.

If you take a prescription medication for asthma or depression, be sure your doctor knows you are quitting smoking. Your prescription medication dose may need to be adjusted.

Those under 18 should use this product under a doctor's care.

Symptoms of nicotine overdose may include vomiting and diarrhea. Young children are more likely to have additional symptoms, including weakness. Also, seizures have been seen in children who swallowed cigarettes.

Keep this and all drugs out of the reach of children. In case of accidental overdose, seek professional assistance or contact a poison control center immediately.

LET'S GET STARTED. Becoming a non-smoker starts today. Your first step is to read through this entire User's Guide carefully.

Next, set your personalized quitting schedule.

Take out a calendar that you can use to track your progress, and identify four dates, using the stickers in the center of this User's Guide:

STEP 1. Your quit date (and the day you'll start using Nicotine Polacrilex Gum).

Choose your quit date (it should be soon). This is the day you will quit smoking cigarettes entirely and begin using **Nicotine Polacrilex Gum** to satisfy your cravings for nicotine. For the first six weeks, you'll use a

piece of **Nicotine Polacrilex Gum** every hour or two. Be sure to follow the directions. Place the Step 1 sticker on this date.

STEP 2. The day you'll start reducing your use of Nicotine Polacrilex Gum. After six weeks, you'll begin gradually reducing your **Nicotine Polacrilex Gum** usage to one piece every two to four hours. Place the Step 2 sticker on this date (the first day of week seven).

STEP 3. The day you'll further reduce your use of Nicotine Polacrilex Gum. Nine weeks after you begin using **Nicotine Polacrilex Gum**, you will further reduce your nicotine intake by using one piece every four to eight hours. Place the Step 3 sticker on this date (the first day of week ten). For the next three weeks, you'll use a piece of

Nicotine Polacrilex Gum every four to eight hours.

End of treatment: The day you'll complete Nicotine Polacrilex Gum therapy. **Nicotine Polacrilex Gum** should not be used for longer than twelve weeks. Identify the date thirteen weeks after the date you choose in Step 1, and place the "EX-SMOKER" sticker on your calendar.

PLAN AHEAD. Because smoking is an addiction, it is not easy to stop. After you've given up cigarettes, you will still have a strong urge to smoke. Plan ahead NOW for these times, so you're not defeated in a moment of weakness. The following tips may help:

- Keep the phone numbers of supportive friends and family members handy.
- Keep a record of your quitting process. Track the number of **Nicotine Polacrilex Gum** pieces you use each day, and whether you feel a craving for cigarettes. If you smoke at all, write down what you think caused the slip.
- Put together an Emergency Kit that includes items that will help take your mind off occasional urges to smoke. Include cinnamon gum or lemon drops to suck on, a relaxing cassette tape, and something for your hands to play with, like a smooth rock, rubber band, or small metal balls.
- Set aside some small rewards, like a new magazine or a gift certificate

from your favorite store, which you'll "give" yourself after passing difficult hurdles.

- Think now about the times when you most often want a cigarette, and then plan what else you might do instead of smoking. For instance, you might plan to take your coffee break in a new location, or take a walk right after dinner, so you won't be tempted to smoke.

HOW Nicotine POLACRILEX GUM WORKS. **Nicotine Polacrilex Gum** sugar-free chewing pieces provide nicotine to your system—they work as a temporary aid to help you quit smoking by reducing nicotine withdrawal

symptoms. **Nicotine Polacrilex Gum** provides a lower level of nicotine to your blood than cigarettes, and allows you to gradually do away with your body's need for nicotine.

Because **Nicotine Polacrilex Gum** does not contain the tar or carbon monoxide of cigarette smoke, it does not have the same health dangers as tobacco. However, it still delivers nicotine, the addictive part of cigarette smoke. Nicotine can cause side effects such as headache, nausea, upset stomach, and dizziness.

HOW TO USE NICOTINE POLACRILEX GUM.

Before you can use **Nicotine Polacrilex Gum** correctly, you have to practice! That sounds silly, but it isn't. **Nicotine Polacrilex Gum** isn't like ordinary chewing gum. It's a medicine, and must be chewed a certain way to work right. Chewed like ordinary gum, **Nicotine Polacrilex Gum** won't work well and can cause side effects. An overdose can occur if you chew more than one piece of **Nicotine Polacrilex Gum** at the same time, or if you chew many pieces one after another. Read all the following instructions before using **Nicotine Polacrilex Gum**. Refer to them often to make sure you're using

Nicotine Polacrilex Gum correctly. If you chew too fast, or do not chew correctly, you may get hiccups, heartburn, or other stomach problems.

- 1) Stop smoking completely before you start using **Nicotine Polacrilex Gum**.
- 2) To reduce craving and other withdrawal symptoms, use **Nicotine Polacrilex Gum** according to the dosage schedule. (See page 10)
- 3) Chew each **Nicotine Polacrilex Gum** piece very slowly several times.
- 4) Stop chewing when you notice a peppery taste, or a slight tingling in your mouth. (This usually happens after about 15 chews, but may vary from person to person.)
- 5) "PARK" the **Nicotine Polacrilex Gum** piece between your cheek and gum, and leave it there.
- 6) When the peppery taste or tingle is almost gone (in about a minute), start to chew a few times slowly again. When the taste or tingle returns, stop again.
- 7) Park the **Nicotine Polacrilex Gum** piece again (in a different place in your mouth).
- 8) Repeat steps 3 to 7 (chew, chew, park) until most of the nicotine is gone from the **Nicotine Polacrilex Gum** piece (usually happens in about half an hour; the peppery taste or tingle won't return.)
- 9) Throw away the used **Nicotine Polacrilex Gum** piece – safely away from children and pets.

**THE FOLLOWING CHART LISTS THE RECOMMENDED USAGE
SCHEDULE FOR NICOTINE POLACRILEX GUM:**

Weeks 1 through 6	Weeks 7 through 9	Weeks 10 through 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours
DO NOT USE MORE THAN 24 PIECES PER DAY.		

To improve your chances of quitting, use at least 9 pieces of **Nicotine Polacrilex Gum** a day. Heavier smokers may need more pieces to reduce their cravings.

Don't eat or drink for 15 minutes before using **Nicotine Polacrilex Gum**, or while chewing a piece. The effectiveness of **Nicotine Polacrilex Gum** may be reduced by some foods and drinks, such as coffee, juices, wine or soft drinks.

**HOW TO
REDUCE YOUR
NICOTINE
POLACRILEX
GUM USAGE.**

The goal of using **Nicotine Polacrilex Gum** is to slowly reduce your dependence on nicotine. The schedule for using **Nicotine Polacrilex Gum** will help you reduce your nicotine craving gradually. Here are some tips to help you cut back during each step:

PLACE THESE STICKERS ON YOUR CALENDAR:



AT THE BEGINNING OF WEEK #1
(QUIT DATE)

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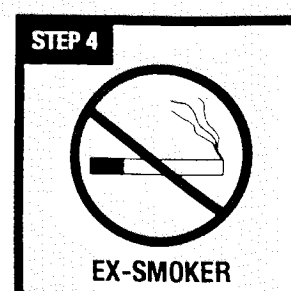
AT THE BEGINNING OF WEEK #7

PLACE THESE STICKERS ON YOUR CALENDAR:



AT THE BEGINNING OF WEEK #10

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12 WEEKS AFTER QUIT DATE

- After a while, start chewing each **Nicotine Polacrilex Gum** piece for only 10 to 15 minutes, instead of half an hour. Then, gradually begin to reduce the number of pieces used.

- Or, try chewing each piece for longer than half an hour, but reduce the number of pieces you use each day.

- Substitute ordinary chewing gum for some of the **Nicotine Polacrilex Gum** pieces you would normally use. Increase the number of pieces of ordinary gum as you cut back on the **Nicotine Polacrilex Gum** pieces.

STOP USING NICOTINE POLACRILEX GUM AT THE END OF WEEK 12. If you still feel the need to use **Nicotine Polacrilex Gum** after Week 12, talk with your doctor.

TIPS TO MAKE QUITTING EASIER.

Within the first few weeks of giving up smoking, you may be tempted to smoke for pleasure, particularly after completing a difficult task, or at a party or bar. Here are some tips to help get you through the important first stages of becoming a non-smoker:

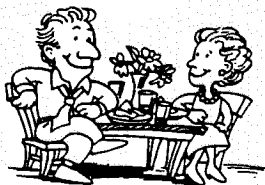
On Your Quit Date:

- Ask your family, friends and co-workers to support you in your efforts to stop smoking.
- Throw away all your cigarettes, matches, lighters, ashtrays, etc.
- Keep busy on your quit day. Exercise. Go to a movie. Take a walk. Get together with friends.

- Figure out how much money you'll save by not smoking. Most ex-smokers can save more than \$1,000 a year.
- Write down what you will do with the money you save.
- Know your high risk situations and plan ahead how you will deal with them.
- Keep **Nicotine Polacrilex Gum** near your bed, so you'll be prepared for any nicotine cravings when you wake up in the morning.
- Visit your dentist and have your teeth cleaned to get rid of the tobacco stains.

Right after Quitting:

- During the first few days after you've stopped smoking, spend as much time as possible at places where smoking is not allowed.



- Drink large quantities of water and fruit juices.
- Try to avoid alcohol, coffee and other beverages you associate with smoking.

- Remember that temporary urges to smoke will pass, even if you don't smoke a cigarette.
- Keep your hands busy with something like a pencil or a paper clip.
- Find other activities which help you relax without cigarettes. Swim, jog, take a walk, play basketball.
- Don't worry too much about gaining weight. Watch what you eat, take time for daily exercise, and change your eating habits if you need to.



- Laughter helps. Watch or read something funny.

WHAT TO EXPECT. Your body is now coming back into balance. During the first few days after you stop smoking, you might feel edgy and nervous and have trouble concentrating. You might get headaches, feel dizzy and a little out of sorts, feel sweaty or have stomach upsets. You might even have trouble sleeping at first. These are typical withdrawal symptoms that will go away with time. Your smoker's cough will get worse before it gets better. But don't worry, that's a good sign. Coughing helps clear the tar deposits out of your lungs.

After A Week Or Two.

By now you should be feeling more confident that you can handle those smoking urges. Many of your withdrawal symptoms have left by now, and you should be noticing some positive signs: less coughing, better breathing and an improved sense of taste and smell, to name a few.

After A Month.

You probably have the urge to smoke much less often now. But urges may still occur, and when they do, they are likely to be powerful ones that come out of nowhere. Don't let them catch you off guard. Plan ahead for these difficult times.

Concentrate on the ways non-smokers are more attractive than smokers. Their skin is less likely to wrinkle. Their teeth

are whiter, cleaner. Their breath is fresher. Their hair and clothes smell better. That cough that seems to make even a laugh sound more like a rattle is a thing of the past. Their children and others around them are healthier, too.

What To Do About Relapse.

What should you do if you slip and start smoking again? The answer is simple. A lapse of one or two or even a few cigarettes has not spoiled your efforts! Discard your cigarettes, forgive yourself and try again.

If you start smoking again, keep your box of **Nicotine Polacrilex Gum** for your next quit attempt.

If you have taken up regular smoking again, don't be discouraged. Research shows that the best thing you can do is to try again. The important thing is to learn from your last attempt.

- Admit that you've slipped, but don't treat yourself as a failure.
- Try to identify the "trigger" that caused you to slip, and prepare a better plan for dealing with this problem next time.
- Talk positively to yourself — tell yourself that you have learned something from this experience.
- Make sure you used **Nicotine Polacrilex Gum** correctly over the full 12 weeks to reduce your craving for nicotine.

- Remember that it takes practice to do anything, and quitting smoking is no exception.

WHEN THE STRUGGLE IS OVER.

Once you've stopped smoking, take a second and pat yourself on your back. Now do it again. You deserve it.

Remember now why you decided to stop smoking in the first place. Look at your list of reasons. Read them again. And smile.

Now think about all the money you are saving and what you'll do with it. All the non-smoking places you can go, and what you might do there. All those years you may have added to your life, and what you'll do with them.

Remember that temptation may not be gone forever. However, the hard part is behind you so look forward with a positive attitude, and enjoy your new life as a non-smoker.

QUESTIONS & ANSWERS.

1. How will I feel when I stop smoking and start using Nicotine Polacrilex Gum?

You'll need to prepare yourself for some nicotine withdrawal symptoms. These begin almost immediately after you stop smoking, and are usually at their worst during the first three or four days. Understand that any of the following is possible:

- craving for cigarettes
- anxiety, irritability, restlessness, mood changes, nervousness
- drowsiness
- trouble concentrating
- increased appetite and weight gain
- headaches, muscular pain, constipation, fatigue.

Nicotine Polacrilex Gum can help provide relief from withdrawal symptoms such as irritability and nervousness, as well as the craving for nicotine you used to satisfy by having a cigarette.

2. Is Nicotine Polacrilex Gum just substituting one form of nicotine for another?

Nicotine Polacrilex Gum does contain nicotine. The purpose of **Nicotine Polacrilex Gum** is to provide you with enough nicotine to help control the physical withdrawal symptoms so you can deal with the mental aspects of quitting. During the 12 week program, you will gradually reduce your nicotine intake by switching to fewer pieces each day. Remember, don't use **Nicotine Polacrilex Gum** together with nicotine patches or other nicotine containing products.

3. Can I be hurt by using Nicotine Polacrilex Gum?

For most adults, the amount of nicotine in the gum is less than from smoking. Some people will be sensitive to even this amount of nicotine and should not use this product without advice from their doctor. (See page 4) Because **Nicotine Polacrilex Gum** is a gum-based product, chewing it can cause dental fillings to loosen and aggravate other mouth, tooth and jaw problems. **Nicotine Polacrilex Gum** can also cause hiccups, heartburn and other stomach problems especially if chewed too quickly or not chewed correctly.

4. Will I gain weight?

Many people do tend to gain a few pounds the first 8-10 weeks after they stop smoking. This is a very small price to pay for the enormous gains that you will make in your overall health and attractiveness. If you continue to gain weight after the first two months, try to analyze what you're doing differently. Reduce your fat intake, choose healthy snacks, and increase your physical activity to burn off the extra calories.

5. Is Nicotine Polacrilex Gum more expensive than smoking?

The total cost of **Nicotine Polacrilex Gum** for the 12 week program is about equal to what a person who smokes one and a half packs of cigarettes a day would spend on cigarettes for the same period of time. Also, use of **Nicotine Polacrilex Gum** is only a short-term cost, while the cost of smoking is a long-term cost, because of the health problems smoking causes.

6. What if I slip up?

Discard your cigarettes, forgive yourself and then get back on track. Don't consider yourself a failure or punish yourself. In fact, people who have already tried to quit are more likely to be successful the next time.

GOOD LUCK!



**RECOMMENDED DOSAGE SCHEDULE FOR
NICOTINE POLACRILEX GUM:**

STEP 1	STEP 2	STEP 3
Weeks 1 to 6	Weeks 7 to 9	Weeks 10 to 12
1 piece every 1 to 2 hours	1 piece every 2 to 4 hours	1 piece every 4 to 8 hours

WALLET CARD

My most important reasons
to quit smoking are:

WALLET CARD

Where to call for help:

American Lung Association
1-800-586-4872

American Cancer Society
1-800-227-2345

American Heart Association
1-800-242-8721